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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/848,832	05/04/2001	Douglas C. Hooper	HOO01-NP002	7484

23973 7590 05/04/2004

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EXAMINER	
SCHEINER, LAURIE A	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 05/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/848,832	HOOPER ET AL.	
	Examiner	Art Unit	
	Laurie A. Scheiner	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 5-18* is/are pending in the application.

4a) Of the above claim(s) *1,2,5-12,17 and 18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claims 1, 2, 5-12, 17 and 18 are withdrawn from consideration. It is noted that newly presented claims 17 and 18 are withdrawn from consideration as being directed to a non-elected invention (antibody fragments) since applicant has received an action on the merits for the originally presented invention. See 37 CFR 1.142(b) and MPEP § 821.03. Claims 3 and 4 have been canceled. Newly added claims 13-16 are considered below.

35 U.S.C. § 101 reads as follows:

> "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

Claims 13-16 are rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter. The antibody, as claimed, has the same characteristics and utility as that found in nature and therefore does not constitute patentable subject matter. In the absence of the hand of man, the naturally occurring antibody is considered non-statutory subject matter. Diamond v. Chakrabarty, 206 USPQ 193 (1980). Additionally, mere purity of a naturally occurring product does not necessarily impart patentability. Ex parte Siddiqui, 156 USPQ 426 (1966). However, when purity results in a new utility, patentability is considered. Merck Co. v. Chase Chemical Co., 273 F. Supp. 68 (1967). See also American Wood v. Fiber Disintegrating Co., 90 US 566 (1974); American Fruit Growers v. Brogdex Co., 283 US 1 (1931); Funk Brother Seed Co. v. Kalo Inoculant Co., 283 US 127 (1984). Amending the claims to recite an isolated limitation is suggested to obviate this rejection.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13-15 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *In re Rasmussen,* 650 F.2d 1212, 211 U.S.P.Q. 323 (C.C.P.A. 1981). *In re Wertheim,* 541 F.2d 257, 191 U.S.P.Q. 90 (C.C.P.A. 1976). Claims 13-16 are drawn toward an antibody having at least a specific amino acid sequence homology to a light chain polypeptide and a heavy chain polypeptide represented by specific sequence identifiers, respectively. The written description requirement under Section 112, first paragraph, sets forth that the claimed subject matter must be supported by an adequate written description that is sufficient to enable anyone skilled in the art to make and use the invention. The courts have concluded that the specification must demonstrate that the inventor(s) had possession of the claimed invention as of the filing date relied upon. Although the claimed subject matter need not be described identically, the disclosure relied upon must convey to those skilled in the art that applicants had invented the subject matter claimed. *In re Wilder, et al.,* 222 U.S.P.Q. 369 (C.A.F.C. 1984). *In re Werthheim, et al.,* 191 U.S.P.Q. 90 (C.C.P.A. 1976). *In re Driscoll,* 195 U.S.P.Q. 434 (C.C.P.A. 1977). *Utter v. Hiraga,* 6 U.S.P.Q.2d 1709 (C.A.F.C. 1988). *University of California v. Eli Lilly,* 119 F.3d 1559, 43 U.S.P.Q.2d 1398 (Fed. Cir. 1997). *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.,* 18 U.S.P.Q.2d 1016-1031 (C.A.F.C. 1991). *Fiers v. Sugano,* 25 U.S.P.Q.2d 1601-1607 (C.A.F.C. 1993). *In re Bell,* 26 U.S.P.Q.2d 1529-1532 (C.A.F.C. 1993). *In re Deuel,* 34 U.S.P.Q.2d 1210-1216 (C.A.F.C. 1995).

Applicants' disclosure fails to provide adequate written support for the invention as now claimed. Again, the disclosure fails to provide an adequate written description for subject matter encompassing antibodies other than the human monoclonal rabies neutralizing antibodies as set

forth by the specification. Moreover, the recitation of "having at least 90% (or 80%) amino acid sequence homology to SEQ ID NO:3 and a light chain polypeptide comprising an amino acid sequence having at least 90% (or 80%) amino acid sequence homology to SEQ ID NO:4" is clearly new matter and applicants fail in pointing out a specific basis in the specification.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims recite "at least 90% (or 80%) amino acid homology" to two particular sequences. However, "homology" or sequence similarity can be calculated by a variety of different methods, whereby the calculated homology between two sequences will be quite different depending on the algorithm used for calculation. Furthermore, the calculation of "homology" is affected by variables such as the relative weight given to sequence gaps versus mismatches, or whether conservative substitutions are weighted differently from nonconservative substitutions. Since no art-recognized convention exists regarding the calculation of percent homology, the recitation "at least 90% (or 80%). . . homology" is vague and indefinite. Additionally, claims 13-15 recite the language "homology" in reference to amino acid sequences. However, "homology" has an art recognized meaning and implies that two sequences possess a common evolutionary origin. That is, in its precise biological meaning "homology" asserts a type of relationship between two or more things. Thus, amino acid sequences are either homologous or they are not. They cannot exhibit a particular level of homology or "percent homology." Instead, two sequences possess a certain level of similarity or identity. Thus, similarity and identity are quantitative properties. Homologous amino acid

segments can range from highly similar to not recognizably similar (where similarity has disappeared through divergent evolution). Improper usage of the term "homology" in sequence comparison leads to confusion with regard to that which is claimed. If applicants are actually referring to the sequence similarity, or identity, of a particular amino acid sequence appropriate statistical documentation should be provided and the following terms should be employed: a level or degree of similarity/identity; an alignment with optimized similarity; a percentage of positional identity in an alignment; the probability associated with a particular alignment. Alternatively, if the applicants are referring to amino acid sequences related by evolution, this should be made clear. It is again noted, however, that the specification as originally filed fails to support the language of the newly submitted claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laurie Scheiner, whose telephone number is (571) 272-0910. Due to a flexible work schedule, the examiner's hours typically vary each day. However, the examiner can normally be reached Monday thru Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (571) 272-0902.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (571) 272-1600.

Correspondence related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Official communications should be directed toward the following central fax number: (703) 872-9306.

LAURIE SCHEINER
PRIMARY EXAMINER